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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/494,243	01/31/2000	Reid Warren von Borstel	1331-300	3188

7590 06/26/2002
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1100 N Glebe Road
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Arlington, VA 22201

EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/26/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/494,243

Applicant(s)

VON BORSTEL ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4, drawn to purine compounds, classified in class 536, subclass 27.21.
 - II. Claims 5-14, drawn to pyrimidine compounds classified in class 536, subclass 28.1.
 - III. Claims 15-31 drawn to pyrimidine/purine compositions classified in class 536, subclass 27.1.
 - IV. Claims 32, 33, 45 and 46, drawn to a method of enhancing delivery of deoxyribonucleosides, classified in class 514, subclass 45.
 - V. Claim 34-36, drawn to a method for treating or preventing radiation-induced cellular damage, classified in class 514, subclass 42.
 - VI. Claim 37, drawn to a method for treating or preventing mutagen-induced cellular damage, classified in class 514, subclass 42.
 - VII. Claims 38-44, drawn to a method for enhancing the healing of damaged tissue classified in class 514, subclass 42.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II represent independent compounds wherein the search for either purine or pyrimidine compounds represents a divergent class/subclass field of search.
3. Inventions I, II and III represent independent wherein the search for either purine or pyrimidine compounds would not encompass a search for a composition containing both purine and pyrimidine compounds. Under 37 CFR 1.141, two or more distinct

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inventions may not be claimed in one national application. The term "distinct" means that two or more subjects as disclosed are related but are capable of separate manufacture, use or sale as claimed, and are patentable

4. Inventions III and IV - VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the deoxynucleoside compound/composition can be used in the divergent methods of treatment set forth in inventions IV-VII.

5. Inventions IV - VII are drawn to distinct methods of using the same composition. The method of enhancing damaged tissue as set forth in Group VII would require a search broader in scope than those for IV or VI since the damage in this group is not limited to radiation induced damage. The method of Group VI is drawn to mutagen induced damage which a multitude of chemical compounds as mutagens. Chemical mutagenicity would require a divergent search from the radiation induced damage of Group IV.

6. Should applicant elect any one of the methods of Groups IV-VII, the compound or composition from which it depends will also be examined.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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9. Claims 21 and 24 are generic to a plurality of disclosed patentably distinct species comprising:

- | | |
|-----------|---|
| Species 1 | NAC, DDC, cysteamine, 2-mercaptoethanol, mercaptoethylamine, dithiothreitol, 2-mercaptoethanesulfonic acid, WR-2721, WR-1065. |
| Species 2 | nicotinamine, 5-hydroxytryptamine, 2-beta-aminoethyl-isothiuronium-Br-Hbr. |
| Species 3 | GLP/B04, GLP/B05, OK-432, Biostim, PSK, Lentinan, Schizophyllan, Rhodexman, Levan, Mannozyim. |
| Species 4 | MVE-2, MNR, MMZ, IL-1, TNF, thymic factor TF-5. |
| Species 5 | glutathione, glutathione peroxidase, glutathione reductase, glutathione transferase, superoxide dismutase, catalase. |
| Species 6 | selenium, CdCl ₂ , MnCl ₂ , Zn acetate, Vitamin A, beta carotene, tocopherol. |
| Species 7 | prostaglandins |
| Species 8 | methylene blue, PABA |

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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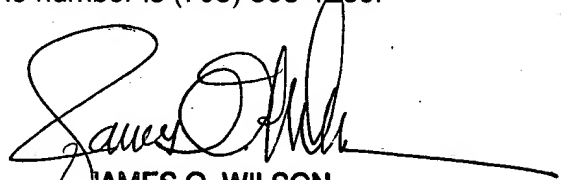
10. A telephone call was made to Leonard Mitchard to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538. The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Primary Examiner signing this action, James O. Wilson can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



JAMES O. WILSON
PRIMARY EXAMINER
Group 1600